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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,811	11/24/2003	Hosheng Tu	XEPMED-126	5365
41648	7590	04/21/2005	EXAMINER	
HOSHENG TU			DEAK, LESLIE R	
15 RIEZ			ART UNIT	
NEWPORT BEACH, CA 92657-0116			PAPER NUMBER	
			3762	

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/720,811

Applicant(s)

TU ET AL.

Examiner

Leslie R. Deak

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 11/24/03
- 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Notes on Claims

1. Applicant has used "means for" language in Claim 1, properly invoking 35 USC 112, sixth paragraph for examination of the claims. However, in order to qualify for interpretation under the 6th paragraph standard, the claims must not be modified by sufficient structure, material, or acts for achieving the specified function. Therefore, claims 2-7, since they recite structure, material, and/or acts for achieving the function, do not qualify for interpretation under 35 USC 112, paragraph six. See MPEP 2181.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 recites the limitation "the effective amount of radiation" in line 1. There is insufficient antecedent basis for this limitation in the claim.

4. Claims 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. In particular, the claims depend on "the method of claim 11" when claim 11 references and depends on claims drawn to an apparatus. Examiner has examined the claims as depending from the apparatus referenced in claim 11.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-6, 8-12, 14, and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,737,140 to Lee et al in view of US 5,376,263 to Fischel. Lee discloses a system and method for obtaining blood from a patient—who may be suffering from an autoimmune disease—while adding an anticoagulant, separating a plasma component, treating the plasma with a photoactive agent, and using the photoactive agent to irradiate pathogens within the plasma, and returning the treated plasma and the other separated blood components to the patient (see column 3, lines 29-57). Lee uses a centrifuge as his means for separating patient whole blood into plasma and red cell portions. Fischel discloses that membrane filtration of blood, in lieu of a centrifuge, in order to preserve the cellular integrity and activity of the separated cells. His filter uses a moving membrane to contact the blood that flows through the filter compartment, allowing cellular matter to migrate through the semipermeable filter membrane into an outflow path. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the filter mechanism disclosed by Fischel as the blood separator in the system disclosed by Lee in order to separate the

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blood components while maintaining structural integrity of the blood cells, as taught by Fischel.

With regard to Claim 1, examiner has looked to the specification in order to determine the scope of applicant's "means for" withdrawing, separating, inactivating, and returning the fluids treated in the invention, as required by 35 USC 112, 6th paragraph. Examiner believes that the Fischel filter performs an equivalent function to the filter disclosed in the specification of the instant application, and has rejected the claims as provided by MPEP 2183.

With regard to applicant's claims 2-5, 8-10, and 17-19, regarding the specific compounds used with and treated by the apparatus, such a statement amounts to a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114.

With regard to claim 16, Lee discloses the claimed invention except for the amount of radiation used. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the amount of radiation claimed by applicant, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. See MPEP 2144.05.

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of Fischel, further in view of US 2002/0043051 A1 to Manica et al. Lee and Fischel disclose the apparatus and method as claimed with the exception of using certain

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compounds as photosensitizing agents. Manica discloses a bag for use in an irradiation procedure and discloses that riboflavin and vitamin K are preferred photosensitizers since they are not toxic to the patient blood, and don't require removal before reinfusion of the treated blood to the patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use Vitamin K and riboflavin as photosensitizing agents in order to prevent toxic reactions with the patient blood, as taught by Manica.

Allowable Subject Matter

8. Claims 7 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 2002/0095108 A1 Tsuchida et al
 - i. Photoreduction device that acts on plasma
- b. US 6,219,584 B1 Lee
 - ii. System and method for separating blood, treating in a photoactivation device, and returning treated blood to patient

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lrd
13 April 2005

Angela D. Sykes

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